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AT 8:30 M WILLIAM Y. WALSH, CLERK

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UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

SHIRE US, INC.,

٧.

Hon. Joel A. Pisano, U.S.D.J.

Plaintiff,

Civil Action No. 02 CV 2023 (JAP)

BARR LABORATORIES, INC.,

Defendant.

DEFENDANT, BARR LABORATORIES, INC.'S ANSWER AND AFFIRMATIVE DEFENSES

Defendant Barr Laboratories, Inc. ("Defendant") by its attorneys, Winston & Strawn, answers the numbered paragraphs of Plaintiff's Complaint as follows:

- 1. Defendant admits the allegations set forth in paragraph 1 of Plaintiff's Complaint.
- 2. Defendant admits that it is a corporation organized and existing under the laws of the State of New York; has a principal place of business in Pomona, New York; has manufacturing facilities at 265 Livingston Street in Northvale, New Jersey; and does business throughout the United States including New Jersey. Defendant further admits that it manufactures generic ADHD medication in Northvale, New Jersey and sells such product in

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New Jersey. Defendant denies the remaining allegations set forth in paragraph 2 of Plaintiff's Complaint.

- 3. Defendant admits that Plaintiff purports to set forth causes of action under 15 U.S.C. §§ 43(a) and (c) and for unfair competition under the laws of the State of New Jersey "and other states". Plaintiff's claims for unfair competition under the laws of states other than New Jersey have been dismissed. Defendant denies that any action of Defendant has given rise to said causes of action. Defendant admits that the Court has jurisdiction pursuant to 15 U.S.C. § 1121, and 28 U.S.C. §§ 1331, 1338(a) and (b). Defendant further admits that venue is proper pursuant to 28 U.S.C. § 1391(b) and (c). Defendant denies the remaining allegations set forth in paragraph 3 of the Complaint.
- 4. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 4 of the Complaint and, therefore, denies same.
- 5. Defendant admits that ADDERALL consists of mixed amphetamine salts, is intended for the treatment of attention deficit disorder with hyperactivity (ADHD), and is a controlled substance available by prescription only. Defendant denies the remaining allegations set forth in paragraph 5 of the Complaint.
- 6. Defendant admits that the ADDERALL product is available in 10 mg and 20 mg dosage strengths and has recently been introduced in 7.5 mg, 12.5 mg and 15 mg dosage strengths. Defendant denies the remaining allegations set forth in paragraph 6 of the Complaint, denies that the colors blue and light orange/peach are distinctive, and denies that Exhibit 1 to the Complaint fairly or accurately shows "the appearance of the ADDERALL tablets."
 - 7. Defendant denies the allegations set forth in paragraph 7 of the Complaint.

- 8. Defendant admits that certain print advertising for the ADDERALL product contains the statement "to be certain you are getting what was prescribed by your doctor, your ADDERALL tablets should look like these . . . ", and further admits that the statement is accompanied by color pictures of ADDERALL tablets in Plaintiff's advertising. Defendant denies the remaining allegations set forth in paragraph 8 of the Complaint.
- 9. Defendant admits that the ADDERALL product has been sold in interstate commerce in the United States and that over 6.7 million prescriptions for ADDERALL were written in 2001. Defendant denies the remaining allegations set forth in paragraph 9 of the Complaint.
 - 10. Defendant denies the allegations set forth in paragraph 10 of the Complaint.
 - 11. Defendant admits the allegations set forth in paragraph 11 of the Complaint.
- 12. Defendant admits that it is offering for sale and selling an FDA approved generic substitute for Plaintiff's ADDERALL mixed amphetamine salts and has advertised its product as an FDA approved generic substitute for ADDERALL. Defendant admits that a photograph of Barr's product and the ADDERALL product is attached to Plaintiff's Complaint as Exhibit 2. Defendant denies the remaining allegations set forth in paragraph 12 of the Complaint.
 - 13. Defendant denies the allegations set forth in paragraph 13 of the Complaint.
- 14. Defendant lacks information sufficient to admit or deny the allegations contained in paragraph 14 of the Complaint and, therefore, denies same. Defendant further answers that it is offering for sale and selling an FDA approved generic substitute for ADDERALL and that no approval or consent of Plaintiff was sought or required in connection therewith.
 - 15. Defendant denies the allegations set forth in paragraph 15 of the Complaint.
 - 16. Defendant denies the allegations set forth in paragraph 16 of the Complaint.

- 17. The allegations in paragraph 17 of the Complaint state a legal conclusion to which no response is required. To the extent a response thereto is required, Defendant denies the allegations set forth in paragraph 17 of the Complaint.
- 18. Defendant repeats and realleges its responses to paragraphs 1 through 17 of the Complaint as if fully set forth herein.
 - 19. Defendant denies the allegations set forth in paragraph 19 of the Complaint.
 - 20. Defendant denies the allegations set forth in paragraph 20 of the Complaint.
 - 21. Defendant denies the allegations set forth in paragraph 21 of the Complaint.
 - 22. Defendant denies the allegations set forth in paragraph 22 of the Complaint.
 - 23. Defendant denies the allegations set forth in paragraph 23 of the Complaint.
- 24. The allegations in paragraph 24 of the Complaint state a legal conclusion to which no response is required. To the extent a response thereto is required, Defendant denies the allegations set forth in paragraph 24 of the Complaint.
- 25. Defendant repeats and realleges its responses to paragraphs 1 through 24 of the Complaint as if fully set forth herein.
- 26. The allegations in paragraph 26 of the Complaint state a legal conclusion to which no response is required. To the extent a response thereto is required, Defendant denies the allegations set forth in paragraph 26 of the Complaint.
 - 27. Defendant denies the allegations set forth in paragraph 27 of the Complaint.
- 28. The allegations in paragraph 28 of the Complaint state a legal conclusion to which no response is required. To the extent a response thereto is required, Defendant denies the allegations set forth in paragraph 28 of the Complaint.

FIRST AFFIRMATIVE DEFENSE

The Complaint fails in whole or in part to state a claim or cause of action upon which relief may be granted.

> WINSTON & STRAWN Attorneys for Defendant, Barr Laboratories, Inc.

By:

Date: September 30, 2002

OF COUNSEL:

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify that the within action is not the subject of any other action pending in any Court, or of any pending arbitration or administrative proceeding.

James S. Richter

Dated: September 30, 2002

CERTIFICATE OF SERVICE

I hereby certify that on September 30, 2002, a copy of Defendant's Answer was served by facsimile and regular mail upon counsel for Shire US, Inc. in an envelope addressed as follows:

Donald A. Robinson, Esq. Robinson & Livelli Two Penn Plaza East Newark, NJ 07105

and

Barbara A. Solomon, Esq. FROSS ZELNICK LEHRMAN & ZISSU 866 United Nations Plaza New York, New York 10017.

James S. Richter (JR-5861)

Dated: September 30, 2002